Date of Approval: May 21, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-328

Oxytocin Injection

(oxytocin)

20 U. S. P. units/mL Injection

Horses, cows, ewes, and sows

Indications: It is indicated to be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

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Sponsored by:
Cross Vetpharm Group Ltd.
Tallaght, Dublin 24, Ireland

FREEDOM OF INFORMATION SUMMARY

1. *GENERAL INFORMATION*:

a. File Number:	ANADA 200-328
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Road Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623
c. Established Name:	Oxytocin injection
d. Proprietary Name:	Oxytocin Injection
e. Dosage Form:	Injectable solution
f. How Supplied:	100 mL multiple dose vial
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains 20 U. S. P. units per mL
i. Route of Administration:	Intravenous, Intramuscular, and subcutaneous
j. Species/Class:	Horses, cows, ewes, and sows
k. Recommended Dosage:	For obstetrical use: Ewes, sows-1.5 to 2.5 mL Cows, horses-5.0 mL For milk let-down Cows-0.5 to 1.0 mL Sows-0.25 to 1.0 mL
l. Pharmacological Category:	Hormone
m. Indications:	Because of the specific action of oxytocin upon the uterine musculature, it is recommended as an aid in the management of following conditions:

	1) To precipitate labor 2) To accelerate normal parturition 3) Postpartum evacuation of uterine debris 4) Postoperative contraction of the uterus following a cesarean section and control of uterine hemorrhage. Oxytocin will contract the smooth muscle cells of the mammary gland to induce milk let-down if the udder is in a proper physiological state.
n. Pioneer Product:	Oxytocin Injection (oxytocin); Phoenix Scientific, Inc., NADA 124-241

2. *TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS*:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement for *in vivo* bioequivalence study for the generic product Oxytocin Injection (oxytocin). The generic product is administered as an injectable solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, Oxytocin Injection, (oxytocin), the subject of Phoenix Scientific, Inc., NADA 124-241, was approved on February 22, 1983.

3. HUMAN SAFETY:

· **Tolerance**

A tolerance is not required because one was not required for the pioneer product.

· **Withdrawal Time**

A withdrawal period is not required because one was not required for the pioneer product.

· **Regulatory Method for residues**

A regulatory method is not required because one was not required for the pioneer product.

Human warnings are provided on the product label as follows: **"For Animal Use Only"**
"Keep Out of Reach of Children."
"Hazardous-Not For Human Use"

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Oxytocin Injection when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Pioneer Labeling for NADA 124-241:
Oxytocin Injection -100 mL vial size and insert

Note: Phoenix Scientific Inc. purchased NADA 124-241 from Merial Ltd., who marketed the pioneer product under the OSBORN tradename. Phoenix is not currently marketing the pioneer product.

Generic Labeling for ANADA 200-328
Oxytocin Injection-100 mL vial size and insert